

510(k) SUMMARY

Lanx's Intervertebral Body/VBR Fusion System

Submitter

APR 20 2009

Lanx, Inc.
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Contact Person: Alan Burkholder

Date Prepared: April 16, 2009

Name of Device

Lanx Fusion System

Common or Usual Name

Vertebral Body Replacement/Intervertebral Body Fusion Device

Classification Name / Regulation Number

Intervertebral body fusion device, 21 CFR 888.3080
Spinal intervertebral body fixation orthosis, 21 CFR 888.3060

Regulatory Class

Class II

Product Codes

ODP, MAX, MQP

Predicate Devices

Lanx, Inc: Lanx Intervertebral Body Fusion Device (K073144)
Lanx, Inc: Lanx VBR (K052384)
Lanx, Inc: Lanx Cervical Intervertebral Body Fusion Device. (K082774)

Other Similar Devices:

Medtronic Sofamor Danek: CAPSTONE® Spinal System (K073291)
Stryker Spine: AVS PL PEEK Spacers (K073470)

Alphatec Spine, Inc: Novel® Spinal Spacer System (K080699)

Description of Device Modification

This submission is intended to seek clearance for a product line extension to the Lanx Intervertebral Body/VBR ("Lanx Fusion System") Fusion System. The product line extension includes the addition of a titanium cage.

All devices in the Lanx Fusion System are made of PEEK (OPTIMA®) per ASTM F2026 and Titanium alloy (Ti-6Al-4V) per ASTM F136. The Fusion System has a hollowed out area to accommodate autogenous bone graft, and transverse grooves to improve fixation and stability. It is available in a variety of different sizes to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The Lanx Fusion System is provided non-sterile.

Statement of Technological Comparison

The additional devices added to the product line have the same intended use and indications, principles of operation, and technological characteristics as the current Lanx Fusion System. The minor difference between the current devices and the devices added to the product line, addition of titanium material, do not raise any new questions of safety or effectiveness. Mechanical testing and engineering analysis demonstrated comparable mechanical properties to the predicate device.

Intended Use / Indications for Use

When used as a cervical intervertebral body fusion device, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one spinal level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. The Lanx Cervical Intervertebral Body Fusion System is to be implanted via an anterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Anterior Cervical Plate System.

When used as a lumbar intervertebral body fusion device, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Lanx Fusion System is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Spinal Fixation System.

When used as vertebral body replacement, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System") is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the

thoracolumbar spine (from T1 to L5) The Lanx Vertebral Body Replacement System may also be used in the thoracolumbar spine (i.e., T1- L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Lanx Vertebral Body Replacement System is also indicated for treating fractures of the thoracic and lumbar spine. The Lanx Vertebral Body Replacement System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column. For either indication the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system

Performance Data

Performance testing was conducted per ASTM F2077 and ASTM F2267. In all instances, the Lanx Fusion System met acceptance criteria and functioned as intended.

Substantial Equivalence

The additional devices included in the product line extension have the same intended uses, indications, technological characteristics, and principles of operation as previously cleared Lanx Intervertebral Body Fusion Device (K073144), Lanx VBR (K052384), and Lanx Cervical Intervertebral Body Fusion Device (K082774). Performance data demonstrate that these additions to the Lanx Fusion System do not raise new issues of safety or effectiveness; hence it is as safe and effective as its predicate devices. Thus, the line item extension devices are substantially equivalent.

Also, devices in Lanx Fusion System have similar size/configurations, material and indication of use to the Medtronic Sofamor Danek: CAPSTONE, Stryker Spine: AVS PL PEEK Spacers, and Alphatec Spine, Inc. Novel System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Lanx, Inc.
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Broomfield, Colorado 80021

APR 20 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K083815

Trade/Device Name: Lanx Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX, MQP
Dated: April 10, 2009
Received: April 13, 2009

Dear Mr. Burkholder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

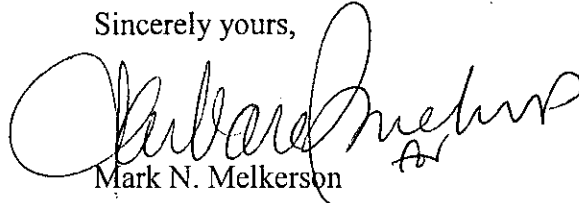
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Alan Burkholder

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson

Director

Division of General, Restorative,

And Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement510(k) Number (if known): K083815

Device Name: Lanx Fusion System

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)**Division of General, Restorative,
and Neurological Devices****510(k) Number** K083815